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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,715	02/13/2002	Jack A. Maggiore	BMT-107	6774

7590 05/17/2005

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,715	MAGGIORE ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-18,20-22 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-18,20-22 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response, filed March 3, 2005 is acknowledged and has been entered. Claims 1-11, 19, 23-31, 33, and 34 were cancelled. Claims 12, 14, 20, and 22 have been amended. Accordingly, claims 12-18, 20-22, and 32 are pending and are under examination.

Rejections Withdrawn

2. The rejections of claims 1-11, 19, and 31 are now moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12-18, 20-22, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague and indefinite in reciting, "the composition being capable of preserving ... for at least about three weeks" because it fails to define an upper limit capacity for the composition to be able to preserve. The term "at least about" in claim 12, as recited, is not defined or supported by the specification, and one of ordinary skill

in the art would not be reasonably apprised of the scope of the invention. The recitation of, "the composition being capable of preserving ... for at least about three weeks" reads on a capacity of preserving for about 10 years.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12-18, 20-22, and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any literal or descriptive support for the recitation of "the composition being capable of preserving ... for at least about three weeks ". Applicant points to page 7, lines 22-25 for support which provides that the biological fluid preserving compositions ... can preserve a specimen when stored for up to about one week at a temperature of about 45C... and [up to] at least about 3 weeks at ambient temperature or below" but fails to provide literal support for such recitation. Applicant also points to Example 3 having Tables 2, 3, and 4 for support wherein the average concentration of TSH is measured at Days 1, 2, 3, 7, 14, and 21 (three weeks) although the data included therein also fails to provide literal or

descriptive support for "the composition being capable of preserving ... for at least about three weeks". Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 12-18, 20-22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steaffens et al. (US Patent 6,579,688) in view of Figard (US Patent 5,616,460).

Steaffens et al. disclose a stabilizing composition suitable for preserving biological fluid specimen having polypeptides and antigens (see Abstract and column 3, lines 55-64). The composition consists essentially of ethylenediaminetetraacetic acid or EDTA as chelating agent and ethanol as cell lysing or dispersing agent. The composition also includes a preservative such as butylated hydroxy anisole or BHA and sodium azide. The composition may also include ethylene glycol (antifreeze agent). See column 4, line 33 to column 5, line 6, and column 2, lines 7-43. Steaffens et al. teach adding EDTA concentrations of 0.05 to about 0.5 weight percent (0.01mM to 100mM), cell lysing agent concentration of 5 to about 25 percent (0.1% to 30% w/v), and a preservative concentration of 0.1 weight percent (0.01% to 10% w/v) (see column 6, lines 12-43).

Steaffens et al. has been discussed supra. Steaffens et al. differ from the instant invention in failing to disclose a concentration of up to about 50 weight percent of antifreeze agent. Steaffens et al. also fail to teach incorporating the preserving composition into a kit format (packaged form).

Figard discloses a buffer composition for reagents wherein ethylene glycol (anti-freeze agent) is used for its superior ability to preserve binding capacity of antibodies to antigens in biological fluids. Figard teaches use of ethylene glycol at concentrations of up to 50 weight percent (4% to about 8% weight per unit volume) (see column 4, lines 53-67). Figard teaches incorporating the reagent into a kit format (reagent packaged form) (see column 6, line 62 to column 7, line 2)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use anti-freeze agent concentration as taught in the composition of Figard in the preserving composition taught by Steaffens because Figard found that ethylene glycol used in such concentrations provide superior preserving capacity in binding interactions between polypeptides. Additionally, specific concentrations of elements in a preserving composition encompass result effective variables which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since prior art teaches that different concentrations of distinct elements in a preserving reagent often vary according to the sample being stored, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the elements contained in the composition disclosed by the prior art by normal optimization procedures.

It would also have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the preserving composition as taught by Steaffens into a kit arrangement as taught by Figard because test kits are conventional and well known in the art for their recognized advantages of convenience and economy.

Response to Arguments

6. Applicant's arguments with respect to claims 12-17 have been considered but are moot in view of the new grounds of rejection.

A) Applicant argues that claim 12 is written in relatively closed "consisting essentially of" language; hence, it is not nearly so broad as the cited sections of Steaffens et al.

In response, claim 12 which is written in "consisting essentially of" language denotes a scope of invention encompassing the aqueous biological fluid preserving composition taught by Steaffens and certainly does not exclude the specific cited teachings by Steaffens et al. To reiterate, Steaffens et al. disclose a stabilizing composition for preserving biological fluid specimen having antigens. The composition consists essentially of EDTA as chelating agent and ethanol as cell lysing agent. The composition also includes butylated hydroxy anisole or BHA as preservative. Steaffens et al. teach that sodium azide is known and used in the art as preservative. The composition may also include ethylene glycol (antifreeze agent). Steaffens et al. teach adding EDTA concentrations of 0.05 to about 0.5 weight percent (0.01mM to 100mM), cell lysing agent concentration of 5 to about 25 percent (0.1% to 30% w/v), and a

preservative concentration of 0.1 weight percent (0.01% to 10% w/v) (see column 6, lines 12-43).

B) Applicant argues that the combination of the teaching of Steaffens with that of Figard does not render obvious the claimed invention because there is no teaching, suggestion, or motivation to have combined the two references to arrive at the specific composition recited in the claims. Applicant specifically contends that Steaffens or Figard does not teach or suggest a composition as set forth in the present claims that is capable of preserving TSH within a blood sample for 3 weeks at 22 C.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Steaffens et al. disclose a stabilizing composition for preserving biological fluid specimen having antigens. The composition consists essentially of EDTA as chelating agent and ethanol as cell lysing agent. The composition also includes butylated hydroxy anisole or BHA as preservative. Steaffens et al. teach that sodium azide is known and used in the art as preservative. The composition may also include ethylene glycol (antifreeze agent). Steaffens et al. teach adding EDTA concentrations of 0.05 to about 0.5 weight percent

(0.01mM to 100mM), cell lysing agent concentration of 5 to about 25 percent (0.1% to 30% w/v), and a preservative concentration of 0.1 weight percent (0.01% to 10% w/v) (see column 6, lines 12-43). Steaffens et al. only differ from the instant invention in failing to disclose a concentration of up to about 50 weight percent of antifreeze agent. Figard has been incorporated herein for disclosure of a composition for use with reagents wherein ethylene glycol (anti- freeze agent) is used for its superior ability to preserve binding capacity of antibodies to antigens in biological fluids at concentrations of up to 50 weight percent (4% to about 8% weight per unit volume). Accordingly, one of ordinary skill in the art at the time of the instant invention would have been motivated to use anti-freeze agent at concentrations taught by Figard in the preserving biological compositions taught by Steaffens because Figard found that ethylene glycol used in such concentrations provide superior preserving capacity in binding interactions between polypeptides. Additionally, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

In response to applicant's argument that Steaffens or Figard does not teach or suggest a composition as set forth in the present claims that is capable of preserving TSH within a blood sample for 3 weeks at 22 C, the discovery of a new inherent property of a known stabilizing composition, discovered to characteristically preserve TSH in blood sample for 3 weeks at 22 C, does not render the product novel, unless otherwise, rendered novel or nonobvious from a modification or variation of its original structure that is structurally different, novel, and nonobvious. Further, a recitation of the intended use of the claimed product must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

C) Applicant argues that there would have been no reasonable expectation of success in preserving TSH in a blood sample for 3 weeks since the references are silent with regard to preservation of TSH.

In response to applicant's argument that the references are silent with regard to preservation of TSH, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference

as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Although the combined references are silent about the capacity of the biological fluid preserving composition to preserve TSH, it does not appear that the claim language or limitations result in a structural difference in the claimed composition when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). Mere recognition of latent properties in the prior art composition does not render nonobvious an otherwise known composition. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

D) The Office acknowledges the typographic error made by Examiner involving claim 18, which should have been included in the original rejection as being anticipated by Steaffens. It was, however, noted in the first Office Action, that each of Steaffens et al. and Figard teach use of sodium azide as a preservative. Accordingly, claim 18 is being properly included with claims 12-17, 20-22, and 32 in the current 35 USC 103 rejection as being unpatentable over Steaffens in view of Figard.

7. No claims are allowed.

8. Applicant's submission of the requirements for the joint research agreement prior art exclusion under 35 U.S.C. 103(c) on March 3, 2005 prompted the new grounds of rejection under 37 CFR 1.109(b) presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
May 11, 2005

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5/13/05